Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Comparison Different Doses Of Intrathecal Dexmedetomidine On Change Of Hemodynamic Parameter And Block QualityAnd neonate’s APGAR After Spinal Anesthesia With Ropivacaine In Cesarean Section

Protocol summary

Study aim

Comparison Different Doses Of Intrathecal Dexmedetomidine On Change Of Hemodynamic Parameter And Block QualityAnd neonate’s APGAR After Spinal Anesthesia With Ropivacaine In Cesarean Section

Design

This study is clinical trial and double-blind .120 patients will enllore non-emergency cesarean section under spinal anesthesia at Taleghani hospital in Arak.

Settings and conduct

This study is clinical trial and double-blind .120 patients will enllore non-emergency cesarean section under spinal anesthesia at Taleghani hospital in Arak.We divide patients in 4 groups by block random pattern.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-35 years; ASA class I and II; patients undergoing cesarean section Exclusion criteria:Refusal of the patient to perform spinal anesthesia; failure to perform spinal anesthesia; history of taking beta-blockers and alpha-2 agonists and calcium channel blockers; cardiovascular disease; coagulation disorders; localized infection in the spinal cord; topical infection in the history of allergy to dexmedmotidine and rupivacaine; arrhythmia

Intervention groups

We inject for patients 2/5 milliliter rupivacaine (0/5 percent(12/5 milligram) Intrathecal plus 2/5 micro gram dexmedetomidin in 1/5 milliliter in first group. We inject 2/5 milliliter rupivacaine (0/5 percent(12/5 milligram) plus 5 micro gram dexmedetomidin in 1/5 milliliter in second group. We inject 2/5 milliliter rupivacaine (0/5 percent(12/5 milligram) plus 7/5 micro gram dexmedetomidin in 1/5 milliliter in third group. We inject 2/5 milliliter rupivacaine (0/5 percent(12/5 milligram) plus 1/5 milliliter normal salin in forth group.

Main outcome variables

Comparison Different Doses Of Intrathecal Dexmedetomidine On Change Of Hemodynamic Parameter And Block QualityAnd neonate’s APGAR After Spinal Anesthesia With Ropivacaine In Cesarean Section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N72**
Registration date: **2018-03-13, 1396/12/22**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-13, 1396/12/22**
Update count: **0**

Registration date

2018-03-13, 1396/12/22

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Different Doses Of Intrathecal Dexmedetomidine On Change Of Hemodynamic Parameter And Block QualityAnd neonate’s APGAR After Spinal Anesthesia With Ropivacaine In Cesarean Section

Public title

Comparison Different Doses Of Intrathecal Dexmedetomidine On Change Of Hemodynamic Parameter And Block QualityAnd neonate’s APGAR After Spinal Anesthesia With Ropivacaine In Cesarean Section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-35 years ASA class I and II Patients undergoing cesarean section

Exclusion criteria:

Refusal of the patient to perform spinal anesthesia Failure to perform spinal anesthesia History of taking beta-blockers and alpha-2 agonists and calcium channel blockers Cardiovascular disease Coagulation disorders Localized infection in the spinal cord Topical infection in the history of allergy to dexmedmotidine and rupivacaine arrhythmia Psychological problems Fetal distress Peripheral and central neuropathy Symptoms for the onset of labor Hypertension Preeclampsia Restriction of intrauterine growth Contraindication of spinal anesthesia Polyhydramnios Macrosomia

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is not aware of the treatment received.Participant and Analyzer are blind (double blind).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Approval date

2017-11-22, 1396/09/01

Ethics committee reference number

IR.ARAKMU.REC.1396.169

Health conditions studied

1

Description of health condition studied

Cesarean Section

ICD-10 code

O82

ICD-10 code description

Single delivery by caesarean section

Primary outcomes

1

Description

Motor block

Timepoint

after start surgery

Method of measurement

bromeg scale

2

Description

sensory block

Timepoint

after start surgery

Method of measurement

bromeg scale

3

Description

pain

Timepoint
recovery and 2 hours after surgery
Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: We inject for patients 2/5 milliliter rupivacaine (0/5 percent(12/5 milligram) Intrathecal plus 2/5 micro gram dexmedetomidin in 1/5 milliliter (total volume 4 milliliter)in first group.
Category
Treatment - Drugs

2

Description
Intervention group: We inject 2/5 milliliter rupivacaine (0/5 percent(12/5 milligram) plus 5 micro gram dexmedetomidin in 1/5 milliliter (total volume 4 milliliter)in second group.
Category
Treatment - Drugs

3

Description
Intervention group: We inject 2/5 milliliter rupivacaine (0/5 percent(12/5 milligram) plus 7/5 micro gram dexmedetomidin in 1/5 milliliter (total volume 4 milliliter)in third group.
Category
Treatment - Drugs

4

Description
Control group: We inject 2/5 milliliter rupivacaine (0/5 percent(12/5 milligram) plus 1/5 milliliter normal salin (total volume 4 milliliter)in forth group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Dr Hesamodin Modir
Street address
Taleghani hospital, Emam khomeini street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Arjmandzadegan
Street address
Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak
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arjmandzadegan@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Yazdi
Position

Assisstant professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person
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Person responsible for updating data

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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
When we publish article in journal.

When the data will become available and for how long
After the article is published

To whom data/document is available
researcher in university

Under which criteria data/document could be used
If there are additional questions

From where data/document is obtainable
Dr Modir

What processes are involved for a request to access data/document
They have to write letters to the professors and the university

Comments